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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

September 26, 2006

MEMORANDUM

TO:

SUBJECT: Cyphenothrin: Revisions for "Occupational and Residential Exposure

Assessment for Proposed Section 3 Registration of Cyphenothrin on Domestic Pets (3/20/2006, D317077)"; DP Barcode: 319222, PC Code:

129013

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This document serves as a revision to the previous document, "Occupational and Residential Exposure Assessment for Proposed Section 3 Registration of Cyphenothrin on Domestic Pets (3/20/2006, D317077)." The purpose of this update is to adjust the March risk assessment to reflect changes resulting from a residential handler default assumption correction and a decision to disregard the concept of a 31-day average residue level for toddler exposure to companion animals. These factors were used in the previous risk assessment to estimate toddler residential risk estimates for postapplication exposure to cyphenothrin.

One of the default assumptions used in the previous risk assessment (D317077) for the estimation of cyphenothrin residential postapplication exposure/ risk was incorrectly identified. In the previous risk assessment, toddler short-term hand-to-mouth exposures were estimated based upon a frequency of 20 events/ hour for 2 hours/ day. While this default factor is accurate for estimating toddler oral exposure from hand-to-mouth

activity on treated indoor hard surfaces and carpet, the correct default assumption for toddler exposure from hand-to-mouth activity to treated companion animals should be based upon a frequency of 1 event/ hour for 2 hours/ day. When applied to the algorithm used to estimate toddler risk for this scenario, the margin of exposure (MOE) is altered. As was performed in the risk assessment, the resulting MOEs were combined (dermal + oral) to estimate the body burden expected from exposure to multiple routes of exposure for the scenarios. The combined MOE in the risk assessment for toddler exposure from dermal (hug) and hand-to-mouth activities to treated companion animals was estimated to be 36. The combined MOE, when corrected for default assumption, results in a combined MOE of 70. Since the recalculated combined MOE for the scenario is less than 100, as was the case in the risk assessment, toddler exposure from dermal (hug) and hand-to-mouth activities to treated companion animals continues to be of concern to HED. The default factors used for the residential postapplication assessment are taken from the HED Exposure Science Advisory Committee SOPs including the following interim changes: SOP12: Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments (2/22/2001) and SOP13: Postapplication Exposure Assessment For Children From Pet Treatments (1/2002).

In the previous risk assessment, a 31-day average residue level concept was presented to better characterize the risk estimated for toddlers from hand-to-mouth activity to a cyphenothrin-treated dog. The cyphenothrin risk assessment team revisited the use of the 31-day average residue level estimate for toddler hand-to-mouth activity to a treated dog in the risk assessment. Ultimately, it was decided that this estimate was not appropriate based upon the timing of effects seen in the 90-day sub-chronic dog study (MRID 42717503), from which the endpoint and dose were selected. The first effects (emesis) were seen in the study on Day 0 for females and on Day 1 for males. Since effects were seen so early in the study, the most protective risk estimate is the combined MOE estimated for Day 0 and, therefore, the 31-day average should be disregarded. The 31-day average residue level was not reassessed for any changes due to correction for the default assumption.

Conclusion

The combined MOE estimated for toddler exposure from dermal activity (hug) and hand-to-mouth activities to treated companion animals, when corrected for default assumption, results in a value of 70. Since the recalculated combined MOE for the scenario is less than 100, it is of concern to HED.